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The Department of Defense Pharmacoeconomic Center

PEC UPDATE

August 2002, Vol. 02, Issue 5, www.pec.ha.osd.mil

In This Issue . . .

Penny-Wise (Editorial)

CAPT Joe Torkildson steps through the BCF policy on providing all forms and strengths of BCF medications—and explains why paying attention to new strengths of existing drugs can benefit both MTFs and patients.

Page 2

Cost Effective Use of Selective Serotonin Reuptake Inhibitors for Depression

Drastic price decreases for generic fluoxetine and the recent award of a DoD/VA mandatory source contract for fluoxetine 10- and 20-mg capsules (<$0.04 per 20-mg capsule) have changed the relative cost-effectiveness of drugs in this class. Since all four commonly used SSRIs (citalopram, fluoxetine, paroxetine, and sertraline) appear equally likely to be effective in treating depression and similar with respect to the rate of adverse effects (although individual side effect profiles vary), it seems reasonable to conclude that choices among the SSRIs can be made primarily on the basis of drug cost for those patients newly diagnosed with depression and those requiring a change in therapy in whom there is no clinical reason to prefer (or avoid) a particular agent.

Page 3

Simvastatin Labeling Changes

When it comes to medical knowledge, more is always better. (**Editor's Note:** so says Dr.T. I brought up Frankenstein, but was overruled on a technicality. ST).

Product labeling for simvastatin (Zocor) was recently revised to clarify the risk of muscle-related adverse effects and drug interactions. This letter to the field reviews the labeling changes (which appear to result from the availability of new clinical trial data, not from significant new findings or increases in the incidence of adverse effects) and concludes that whether or not to adjust therapy based on the recent changes is a question to be addressed by the clinician and the patient after considering benefit vs. risk.

Page 4

Coming Up

EBM = Evidence-Based Medicine

It's a good thing.

Barb's Barbs: Combination Hormone Replacement Therapy & the WHI and HERS II Studies

Dr. Roach comments on the recent hormone replacement therapy results. In early July, the NIH stopped the combination HRT arm of the Women's Health Initiative (WHI) Study several years prior to its intended completion due to an increased risk of invasive breast cancer. The trial also found small increases in coronary heart disease (CHD), stroke, and pulmonary embolism and further confirmed results of the Heart and Estrogen/Progestin Replacement Therapy (HERS-II) study indicating no evidence of cardiovascular protection from HRT in older women with CHD.

Page 5

Q&A

Notifying Prime Vendors about Usage Requirements

Our guest author this month is CDR Brian Kerr from DSCP, who explains how Prime Vendors are (should be) notified of potential changes in MTF usage requirements when a product is added to the Basic Core Formulary or when a mandatory source contract is awarded.

Recent Questions Concerning Blood Glucose Strips

LCDR Ted Briski follows up on his article in the May 2002 PEC Update with answers to some questions about the status of Precision blood glucose strips on the Basic Core Formulary.

Page 6

Waivable Meds in Air Crew Members

LtCol Ed Zastawny's last excellent and succinct article as a PEC staffer, in which he examines the differences between Army, Navy, and Air Force policy regarding medication use in air crew members, points readers to web resources, and explains how whether or not a drug is waivable is taken into account when choosing drugs for the Basic Core Formulary.

Page 7

New Drug Watch

Angela Allerman turns her attention to the pharmaceutical pipeline in the unending effort to keep up with (or at least keep track of) new drugs that are expected to have an impact on DoD in the next year or so. Also in this article: a herd (a flock? a gaggle?) of new generics (tramadol, ciprofloxacin, amoxicillin/clavulanate, misoprostol, lisinopril & tizanidine); a few new indications (e.g., gabapentin for post-herpetic neuralgia); and a handful of new strengths and formulations.

Page 8

Excellent Quote of the Month

"The ability to review a patient's complete medication profile (particularly as so many of our beneficiaries are seen in multiple facilities—both military and civilian) is an incredible asset as we review treatment regimens for efficacy, toxicity and the ever problematic drug interactions.

I personally use this option with essentially every patient I interview!"

Ms. Nancy Radebaugh, Ft Hood

From "On Line Patient Profiling," page 9"

PEC Update Information

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Would you like to receive the e-mail newsletter direct to your Inbox? Let us know by e-mailing Carol Scott, the PEC secretary, at carol.scott@amedd.army.mil.

Editors' E-mails

CAPT Joe Torkildson
Joseph.Torkildson@amedd.army.mil

Shana Trice, PharmD
Shana.Trice@amedd.army.mil

PDTS Corner

Update on the Pharmacy Data Transaction Service

Data Integrity Effort from the Field: Our guest author this month is CAPT Roger Hirsh MSC USN, Naval Medical Center Portsmouth, who teams up with Hector Morales, PDTS CSSC Help Desk Manager to explain some of the efforts CAPT Hirsh has taken to significantly decrease the number of Data Integrity issues at his and other sites and to provide some hints on dealing with the PDTS Data Integrity report by approaching it as a system problem.

On-Line Patient Profiling - It seems not everyone has heard about this new profile review option yet. Well, it's deeply cool (see all your patient's prescriptions, no matter where they were filled), madly useful (as attested by at least one clinician—see the sidebar for the quote of the month), and should already be available at your site (if not, ask WHY!).

PDTS Management Reports - Managers at various levels of DoD Pharmacy are starting to access PDTS data warehouse to generate their own management reports, using Business Objects software via an Internet web server. The PDTS Customer Service Support Center (CSSC) is now offering training sessions at Fort Sam Houston on Business Objects software and how the CSSC uses the program to generate reports. In addition to access using Business Objects, the CSSC continues to provide reports upon request.

Top 10 Level 1 Drug-Drug Interactions by Point of Service for June 2002

Top 50 Drugs by Point of Service, June 2002

Page 9

Submitting Articles
Do you have an article you'd like to see published in the *PEC Update*? Just send CAPT Torkildson or Shana Trice an e-mail, or call the PEC at DSN 421-1271, Commercial (210) 295-1271.

Publication Schedule
The *PEC Update* is published 10 times per year (monthly except July and December. On the grounds that no one is paying much attention those months, anyway...).

Errata

In the June 02 PEC Update article, DoD P&T Highlights, under Therapeutic Interchangeability of Statins, the parenthetical comment "such as greater increases in LDL cholesterol attainable with atorvastatin" is, of course, ridiculously incorrect. It should read "such as greater reductions in LDL cholesterol attainable with atorvastatin." But I doubt this confused anyone, really.

Our Disclaimer

The opinions expressed in this work are the views of the author(s), and do not necessarily reflect the views of the Department of Defense, the Army, Navy, Air Force, or the TRICARE Management Activity. Information presented in this work is meant for academic and educational purposes only. It is not intended nor should it be used as the definitive reference for the treatment or prophylaxis of various diseases. Use of specific product brand names are for identification purposes only unless otherwise indicated.

PEC Update Home
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The Department of Defense Pharmacoeconomic Center PEC Update
August 2002, Vol. 02, Issue 5, www.pec.ha.osd.mil

EDITORIAL

Penny-Wise

2

Editors' Letters

Please send your letters to the editors to Dr. Torkildson at **Joseph.Torkildson@amedd.army.mil**

CAPT Joe Torkildson, MC, USN
Director, Clinical Operations Division
DoD Pharmacoeconomic Center

I spent some time in this column last month talking about policies, and pointing out some problems that can result if we tie ourselves so tightly to the "letter of the law" that we adversely affect patients. This month I'm going to take the opposite side, and talk a bit about what might happen when we choose to ignore policies to the ultimate detriment of our patients (or our budgets).

The policy I'm going to discuss is the 1998 Health Affairs policy regarding the Basic Core Formulary (BCF). If you would like to review this policy in its entirety before going on, you can find it on the **BCF page on the PEC website** (click on "BCF Policy Letter") or on the TRICARE website at http://www.tricare.osd.mil/policy/fy98/bfc98034.html. Now, this isn't your perfect policy. It has the same ambiguities and inconsistencies that bedevil a lot of the policies that we rely on to tell us what to do. But it does have some very clear statements that are each in the policy for a very good reason.

The policy states, "The BCF meets the majority of patients' primary care needs and is a mandatory component of all full service military pharmacy operations". While we have lots of discussions at the PEC about what is meant by 'primary care needs', we all agree that the 'mandatory component' part is intended to ensure that beneficiaries will enjoy a uniform pharmacy benefit wherever they go in the MHS. This is particularly important for those medications used to treat chronic conditions. Patients need to know that if they are on BCF medications that they will be able to obtain them regardless of which MTF they might be transferred to.

The policy also states, "Items on the BCF are first line agents that are the preferred choice of therapy. Other agents may be added to the MTF formulary based on the clinical services and scope of care provided by that facility." The BCF is an inclusionary formulary, not an exclusionary one. Local P&T Committees are free to add drugs to their local formulary if they feel they are necessary to meet the needs of their patient population. What they are not free to do is elect not to add BCF drugs to their local formulary and to tell patients that these drugs are not available at their facility.

An extension of that statement, and the crux of this editorial, is the following: "In the case of multiple strength BCF drugs, all strengths need not be stocked but all prescriptions for that agent will be filled, regardless of strength." In other words, unless the DoD P&T Committee specifically limits the BCF listing to certain dosage forms or strengths, MTFs are expected to make all dosage forms and strengths available to their patients. This doesn't necessarily mean that they all need to be on the shelf, but patients must be able to fill prescriptions for

BCF drugs, regardless of strength, within a clinically appropriate timeframe and without undue inconvenience. In at least one case that I've investigated that's not happening, and that's what I'd like to discuss.

The drug in question is Concerta. For those of you out there who are not familiar with pediatrics or the treatment of Attention Deficit/Hyperactivity Disorder (ADHD), Concerta is an extended release methylphenidate product that was placed on the BCF in November 2000. The rationale behind the addition was the observation that almost 45% of children treated with Ritalin SR, which at the time was the longest-acting methylphenidate preparation available besides Concerta, were requiring a noon dose of immediate release methylphenidate in order to get through the school day. The committee was concerned about the potential for drug diversion with this practice, and with the adverse psychological impact that going to the nurse's office at noon to receive medication could have on children. Available data suggested that Concerta's duration of action was such that it increased the likelihood that children receiving it could get through the school day without additional stimulant therapy.

At the time Concerta was added to the BCF it was approved only in 18- and 36-mg capsules. An additional 54-mg strength capsule was approved in December 2000, and a 27-mg capsule was recently approved in April 2002.

I hope you're still with me, because now comes the fun stuff. Based on some other things happening in the area of ADHD therapy, we decided we should prepare and present a review to the DoD P&T in August 02 regarding the ability of the current list of BCF drugs to meet the clinical needs of patients with ADHD. As part of that review, I ran a utilization report from PDTS looking at how ADHD drugs were being prescribed and dispensed in the Military Health System (MHS). I was struck by the fact that 24% of the utilizers in the retail network and 20% of the utilizers in the mail order program were receiving the 54-mg strength, while only 15% of the utilizers at MTFs were filling prescriptions for 54-mg capsules. Upon further investigation, I discovered several MTFs, including 4 that filled Concerta prescriptions for more than 500 unique patients during that time period, who had filled no prescriptions for the 54-mg strength. Two of those large facilities had their local formularies available on the Internet; in both cases the formulary listing for Concerta stated, "18-mg and 36-mg".

By now you may be asking yourself, "Why would these facilities choose to not put the 54-mg strength on formulary?" It's certainly the question I was asking myself at this point. In all cases but one, it wasn't because there was no need for the higher dosage strength. The percentage of patients simultaneously filling prescriptions for both the 18- and 36-mg strengths at those facilities where all strengths were on formulary was 4.2%. This appears to be the baseline rate involved when prescribers are titrating the dose to achieve the best balance between effectiveness and side effects. However, at those facilities where the 54-mg strength was not available, 16.7% of patients received prescriptions for both the 18- and 36-mg strengths. This 12% difference appears to be directly attributable to the nonavailability of the 54-mg strength at those facilities.

What else could it be? It's not the cost. While the unit price for the 54-mg capsule is a little higher ($1.41) than the price of the 18-mg ($1.31) or the 36-mg ($1.38) capsules, the cost of combining an 18 mg and a 36 mg capsule is $2.70/day, vs. $1.42/day for one 54-mg capsule. If we put some patient volumes into the mix the difference becomes even more telling. That 12% difference in the last paragraph equates to 116 patients at those facilities filling two prescriptions instead of one simply because the 54-mg capsules aren't on formulary. If those 116 patients each fill prescriptions for a 90-day supply of 18-mg and 36-mg Concerta, the total cost for 90 days is $28,188. If those same patients instead filled a prescription for 54-mg Concerta, the total cost for 90 days would be $14,772.60. Not having this dosage strength available costs these facilities $13,415.40/quarter. It's not millions, but it's not insignificant, either.

I guess it could be a workload issue. These are all Schedule II drugs; maybe people don't want an additional

strength on the shelf that they have to count. That would be fine, except if you have to keep enough of the other strengths in inventory to fill all those combination prescriptions I'm not sure you save much counting time.

Finally, maybe these facilities simply didn't know that an additional dosage strength was released. If that's the case, we at the PEC will have to take some of the blame. While we've been pretty good about highlighting new formulations of BCF drugs when they are released, we have been less compulsive about publicizing new strengths. The DoD P&T Committee will be reviewing the class of ADHD drugs at their August meeting, and the minutes will include current information regarding all the drugs and strengths of drugs used to treat this condition that are on the BCF.

For several months we've been making the point that facilities shouldn't have drugs sitting around on their shelves gathering dust. If you never fill prescriptions for a particular form or strength of a BCF item, then don't keep it around. But also don't forget the mandate that unless specifically excluded, BCF status for a drug means all dosage forms and strengths. That means if you've made a decision not to keep a dosage form or strength on your shelf and a beneficiary brings in a prescription for it, you need to fill it in time to meet the patient's need for the drug. And that doesn't mean routinely forcing your providers to write two prescriptions and your patients to take two capsules instead of one. Let's play this one by the rules.

Joe Torkildson, MD
Director, Clinical Operations Division
DoD Pharmacoeconomic Center
210-295-2776 or 210-295-1271; DSN 421-
Joseph.Torkildson@amedd.army.mil

Thanks!

I want to thank all those folks who wrote regarding last month's editorial. Of the 9 letters I received, seven felt I had "hit the nail on the head." I really touched a nerve in the case of the other two letters, sent by individuals at the two facilities described but not identified in the editorial.

An individual from the larger referral facility shared that in fact their facility had previously raised this as a patient satisfaction issue because the referring facility was refusing to fill a prescription written for their enrollee by a physician at the referral hospital, and instead was sending the patient back to the referral hospital to pick up refills. The individual who wrote initially from the referring facility also contacted me. Interestingly, he asserted in his letter that "this was never a 'patient care' issue", and that "there was not one patient that was told 'we can not get that for you'."

Just a couple of quick observations: 1) There is no way both of these statements can be true; 2) I don't think either party is deliberately lying to me; and 3) the only other explanation is that people simply don't always know what's going on at their facilities. This just proves my point: it's hard enough to have your people consistently do the right thing even when that is clearly spelled out in your policies. If your policies are unclear, or you have "unwritten" exceptions to written policy, people will follow the policy to the detriment of patients. The one thing I do believe is that the patient wound up back at the referral hospital trying to fill a prescription, and that's the wrong result.

Hopefully these two facilities can begin to concentrate on correcting the problem before anyone else gets caught in the middle, and other facilities with similar issues can do the same. The rest of you: Keep

reading!"

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August 2002, Vol. 02, Issue 5, www.pec.ha.osd.mil

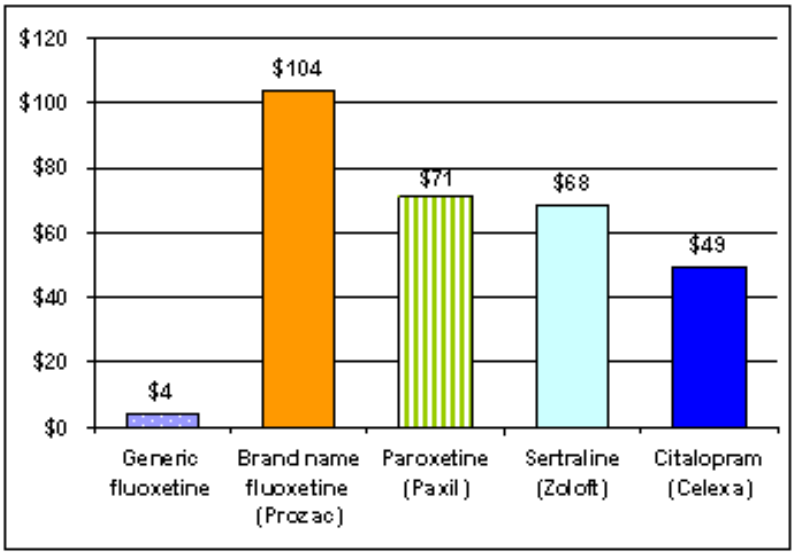
Cost-Effective Use of SSRIs for Depression

Use of Generic Fluoxetine Can Reduce Drug Costs in DoD Military Treatment Facilities

Shana Trice, Clinical Pharmacy Specialist
DoD Pharmacoeconomic Center

- The recent generic availability of fluoxetine has resulted in dramatically decreased prices for fluoxetine—assuming that the generic is used. As of July 2002, the FSS price for a 20 mg capsule of brand name Prozac® was $1.60, compared to less than $0.04 for the generic, a 40-fold difference.

Figure 1: Weighted average cost per SSRI Rx at MTFs, given pricing for generic fluoxetine



Based on SSRI dose distributions and quantities dispensed in MTFs from Mar 02 to May 02 (Source: Pharmacy Data Transaction Service) and DoD FSS or contract prices as of 1 July 2002. Prices for fluoxetine generic are for the generic, contracted product (Mallinckrodt) for the 10- and 20-mg capsules, the only listed generic (Par) for the 40-mg capsules, and brand name Prozac for the 90 mg capsules (Prozac Weekly). Rxs for Sarafem (fluoxetine 20 mg), fluvoxamine (Luvox & generics), and Paxil CR (paroxetine 12.5, 2-, 37.5 mg) are omitted; usage of these products is extremely low (~100 Rxs/month for fluvoxamine; 0-1 Rxs/month for Sarafem & Paxil CR). Prices for brand name fluoxetine are for 10-, 20-, 40-, and 90-mg capsules.

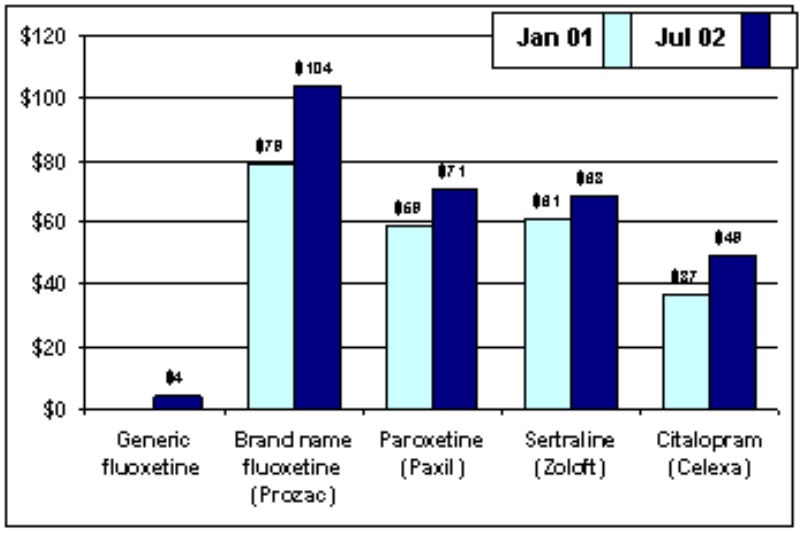
- If the dose distribution and quantities actually dispensed in military treatment facilities (MTFs) are taken into account, the weighted average cost per SSRI prescription is about $4 if generic fluoxetine is used—versus $103 for brand name fluoxetine. See Figure 1 for a comparison to other SSRIs and Figure 2 to see what has happened since Jan 2001.

- According to DoD prime vendor data, MTFs spent approximately $53 million on SSRIs in FY 2001, compared to $76 million for gastric acid reducers, $73 million for lipid lowering agents, and $55 million for antihistamines. Any reduction in the unit cost of SSRIs has the potential for substantially reducing MTF drug expenditures.

- A switch from brand name to generic fluoxetine in itself has the potential to greatly reduce costs. However, this depends on providers continuing to prescribe fluoxetine even though the manufacturer is no longer actively promoting

the brand name medication.

Figure 2: Weighted average cost per SSRI Rx at MTFs, given pricing for generic fluoxetine, Jan 2001 vs. July 2002*



***Jan 2001 results are from the PEC Update, Vol. 01-02, available at www.pec.ha.osd.mil.**

- Is fluoxetine now the most cost-effective SSRI? Here's the argument:
  - SSRIs (citalopram, fluoxetine, paroxetine, and sertraline) appear to be similar in efficacy[1-6], effectiveness,[7,8] and overall tolerability[1-5,9] (as assessed by study discontinuation rates, dropouts due to adverse events, and rates of switching to other antidepressants).
  - All four SSRIs are on the BCF. Therefore the issue is not the selection of a formulary SSRI, or the extent to which prescriptions can be brought back into the MTF from the retail network, but the choice of therapy by providers.
  - The population under discussion is not patients who are currently receiving successful treatment with another SSRI—switching therapy for these patients is likely to be problematic and quite likely counterproductive. Patients likely to be candidates for generic fluoxetine are newly diagnosed patients in whom there is no reason to prefer (or avoid) any particular SSRI, or patients requiring a change in therapy due to intolerance or lack of effect.
  - There are some clear differences among SSRIs:
    - Incidences of specific adverse effects (e.g., sedation) – While SSRIs do not appear to differ in overall tolerability, the reported incidences of specific adverse effects (e.g., sedation) vary.
    - Propensity to cause cytochrome P450 drug interactions – Fluoxetine and paroxetine are more likely to cause P450 drug interactions than citalopram and sertraline, particularly in combination with medications metabolized by or inhibiting the cytochrome P450 2D6 isoenzyme (e.g., certain antidepressants, phenothiazines, antipsychotics, type IC antiarrhythmics).
    - Half-life – Fluoxetine has a half-life of 4-6 days; its active metabolite, norfluoxetine, has a half-life of 4-16 days. In comparison, citalopram, paroxetine, and sertraline have half-lives in the range of 20-35 hours. The long half-life of fluoxetine may blunt the effects of missed doses or treatment discontinuation. On the other hand, fluoxetine requires a much longer washout period than the other SSRIs (several weeks), particularly when switching to monoamine oxidase inhibitors (MAOIs) or thioridazine (see labeling).
  - These differences are of variable importance, depending on the patient; there are likely to be many patients in whom these differences are of little or no concern.

- **In the absence of individual patient factors favoring the selection or avoidance of a particular SSRI, the consequences of treatment with the SSRIs are likely to be equivalent. Therefore, the selection of a SSRI to be used for newly diagnosed patients essentially depends on the relative cost of the agents.**

- Based on weighted average cost per prescription, generic fluoxetine costs 12 times less than citalopram, 16 times less than sertraline, 17 times less than paroxetine, and 24 times less than brand name Prozac®.

- Generic fluoxetine meets all FDA standards to be considered therapeutically equivalent to the brand name product. While the appearance of generic fluoxetine will not be exactly the same as brand name Prozac®, this is unlikely to be a consideration for patients not previously treated with fluoxetine.

- A DoD/VA mandatory source contract for fluoxetine 10- and 20-mg capsules has been awarded to a single manufacturer, Mallinckrodt. (See Table 1.) In addition to securing low prices, consistent use of a single brand of generic fluoxetine across MTFs ensures that patients do not encounter frequent changes in the appearance of their medications, either as a result of local purchases of different generic brands or as a result of moving from one MTF to another.

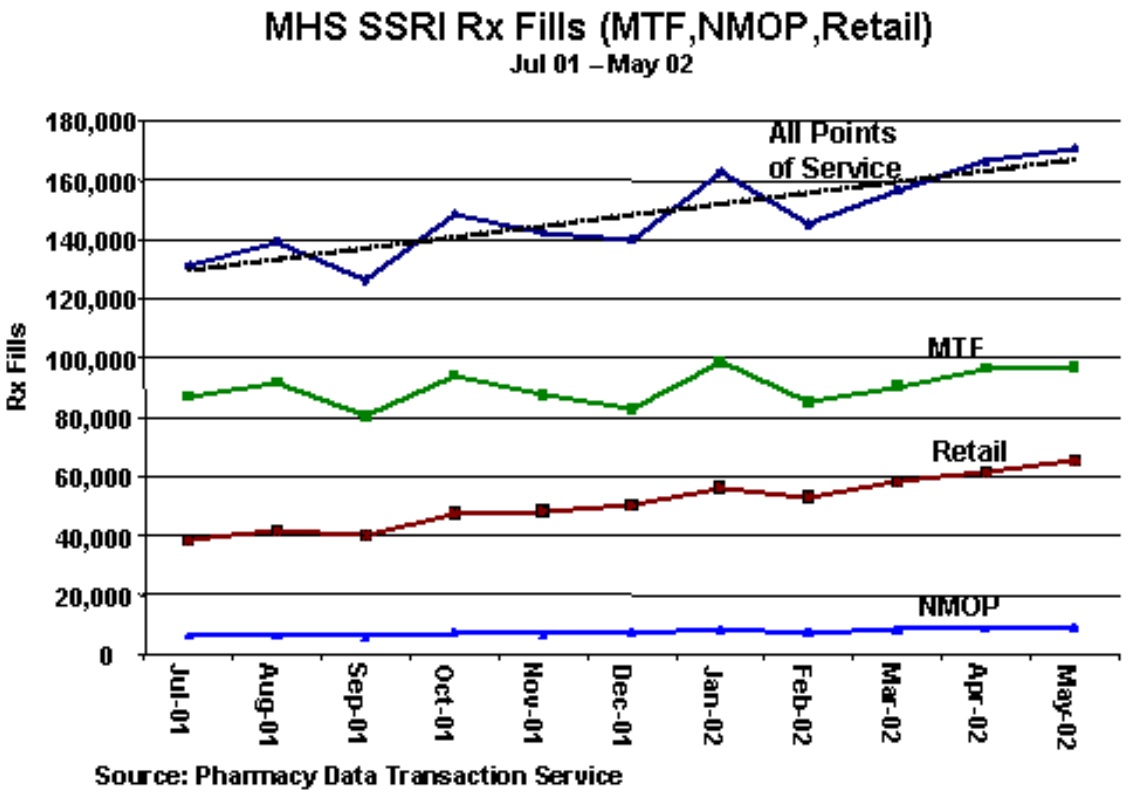
- **Bottom Line: Generic fluoxetine is the most cost-effective SSRI for DoD MTFs. MTFs can reduce drugs costs by using generic fluoxetine for patients newly diagnosed with depression unless there is a clinical reason to use another SSRI.**

Table 1: DoD/VA Contract Information for Fluoxetine 10- and 20-mg capsules

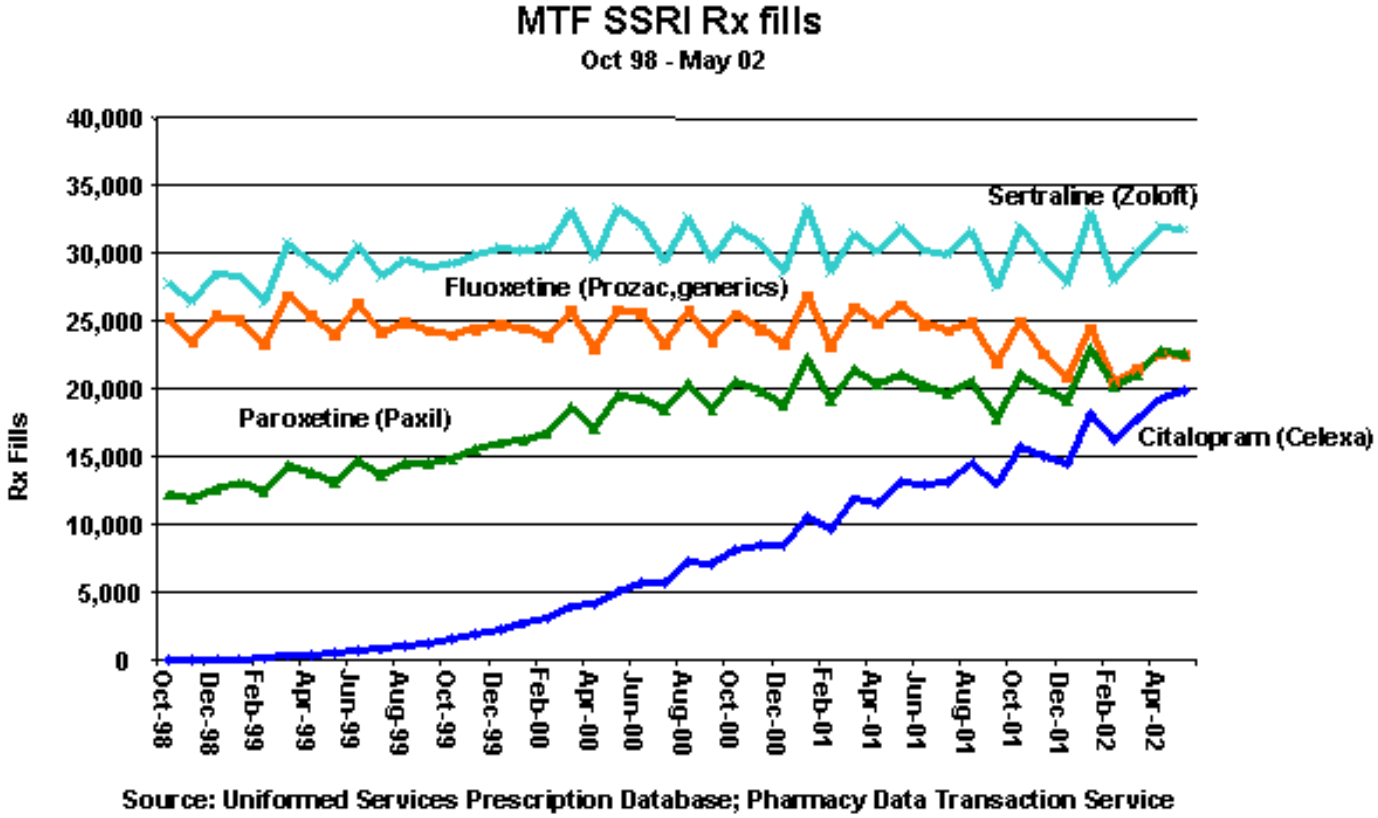
Contract Information	Drug strength, package size	NDC	Price
Contracted Product: Fluoxetine 10mg, 20mg caps **Applicability:** All DoD & Department of Veterans Affairs activities **Type of Award:** Mandatory source procurement. **Effective Date:** 10 Jun 02 – 09 Jun 03 **Length of Contract:** One year with four option years **Manufacturer:** Mallinckrodt, Inc.	10mg 100's	00406-0661-01	$ 2.54
	10mg 500's	00406-0661-05	$ 12.50
	20mg 100's	00406-0663-01	$ 3.20
	20mg 500's	00406-0663-05	$ 15.52

SSRI Usage and Costs in DoD MTFs: Potential Impact of Generic Fluoxetine

- The overall use of SSRIs is increasing in all DoD points of service, including MTFs:



- MTFs do not appear to have an overwhelming preference for any particular SSRI. Use of citalopram, which is less costly than other brand name SSRIs, has increased over time.

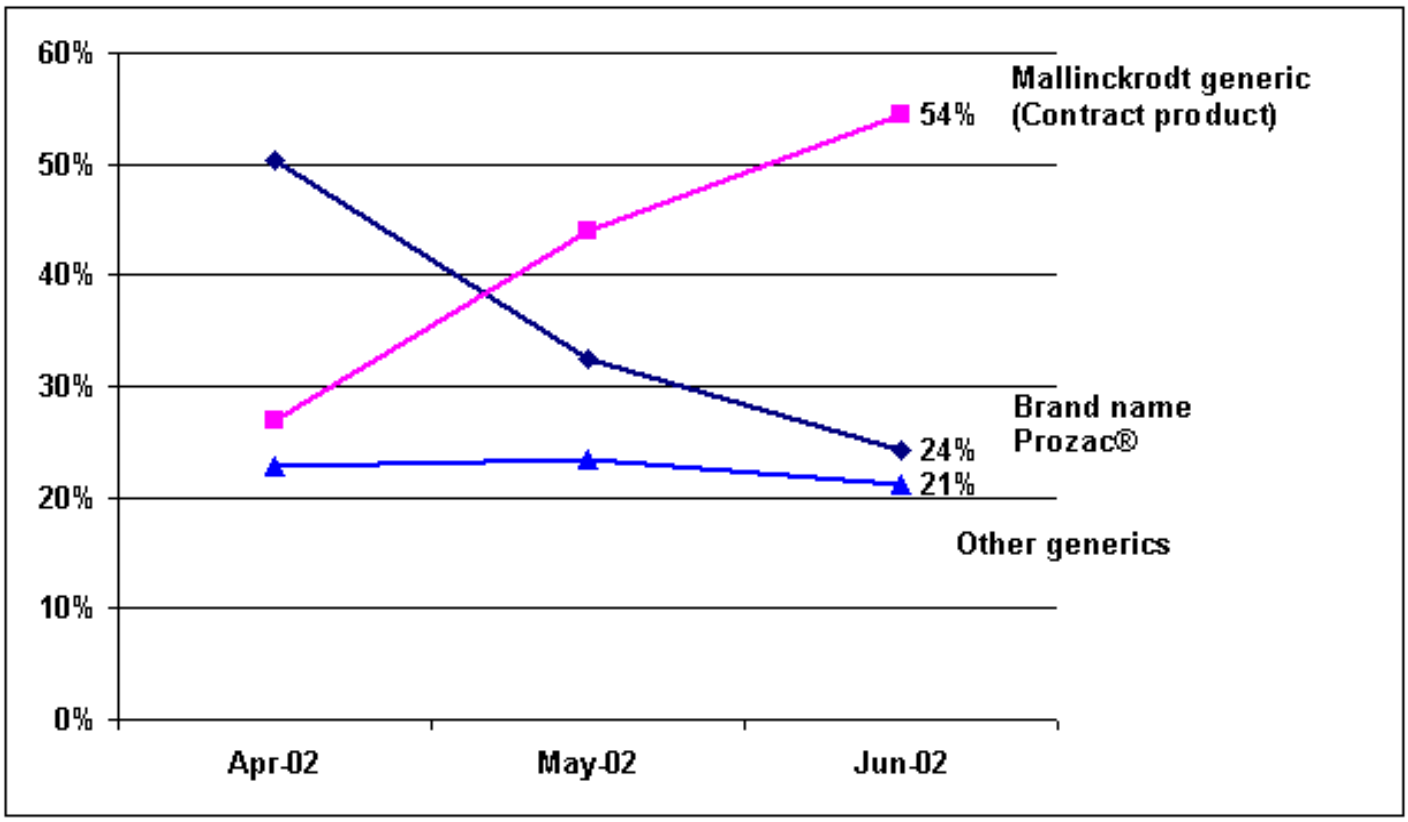


- **The actual financial impact of generic fluoxetine** is difficult to predict, since it will depend on how rapidly MTFs start using the generic, which generic they purchase, and the extent to which providers either continue to use or

begin using generic fluoxetine relative to other SSRIs.

- **How rapidly are MTFs switching to the generic?** First, a methodological note: Due to data integrity issues, MTF prescribing data may not accurately reflect the percentage of prescriptions dispensed for generic vs. brand name products. It is probably more accurate to look at prime vendor purchase data (what MTFs are buying). So, looking at recent prime vendor data:

Total MTF market share for fluoxetine generics vs. brand, by 10- and 20-mg capsules purchased, Apr 02 - Jun 02*



*Excludes 40-mg capsules, Sarafem®, and Prozac Weekly®. Utilization of any of these is low.

- During June 2002, about 75% of 10- and 20-mg fluoxetine capsules purchased were generics (about 54% were the contract product, Mallinckrodt). To maximize uniformity of product appearance across the system (particularly important in this drug class), MTFs should buy the contract brand (yes, even if another generic costs slightly less!).

Shana Trice, Pharm.D., BCPS
DoD Pharmacoeconomic Center
210-295-2788 or 210-295-1271; DSN 421-
shana.trice@amedd.army.mil

Notes

This discussion does not include fluvoxamine (Luvox, generics), which has minimal use in DoD and is not indicated for depression. FDA approval of a sixth SSRI for depression, escitalopram (an isomer of citalopram), is expected in the near future.

Data used in the graphs is primarily derived from the Pharmacy Data Transaction Service (PDTS), supplemented by data from the Uniformed Services Prescription Database (USPD). The PDTS data warehouse contains prescription data from all three DoD points of service (MTFs, NMOP, and the retail pharmacy network) starting in July 2001, while USPD contains MTF prescription data starting in Oct 98. For more information about PDTS, visit the DoD Pharmacoeconomic Center website at www.pec.ha.osd.mil or contact the PDTS Customer Service Support Center at 1-866-ASK4PEC (1-866-275-4732).

References

1. Mulrow CD, Williams JW, Jr., Trivedi M, et al. Treatment of Depression: Newer Pharmacotherapies. Evidence Report/Technology Assessment No. 7. (Prepared by the San Antonio Evidence-based Practice Center based at The University of Texas Health Science Center at San Antonio under Contract 290-97-0012.) AHCPR Publication No. 99-E014. Rockville, MD: Agency for Health Care Policy and Research. February 1999. Available from the National Library of Medicine's Health Service/Technology Assessment Text service at http://text.nlm.nih.gov (use search or download function).
2. Fava M, Rosenbaum J, Hoog S, et al. Fluoxetine versus sertraline and paroxetine in major depression: tolerability and efficacy in anxious depression. J Affect Disorders 2000; 59:119-26.
3. Hotopf M, Hardy R, Lewis G. Discontinuation rates of SSRIs and tricyclic antidepressants: a meta-analysis and investigation of heterogeneity. Br J Psychiatry 1997; 170:120-7.
4. Anderson I. Selective serotonin reuptake inhibitors versus tricyclic antidepressants: a meta-analysis of efficacy and tolerability. J Affect Disorders 2000; 58:19-36.
5. Trindade E, Menon D. Selective serotonin reuptake inhibitors (SSRIs) for major depression. Canadian Coordinating Office for Health Technology Assessment. August 1997. Available at: http://www.ccohta.ca (use search function under “publications”).
6. Fava M, Hoog S, Judge R, et al. Acute efficacy of fluoxetine versus sertraline and paroxetine in major depressive disorder including effects of baseline insomnia. J Clin Psychopharmacol 2002; 22:137-47.
7. Nurnberg H, Thompson P, Hensley P. Antidepressant medication change in a clinical treatment setting: a comparison of the effectiveness of selective serotonin reuptake inhibitors. J Clin Psychiatry 1999; 60:574-9.
8. Kroenke K, West S, Swindle R, et al. Similar effectiveness of paroxetine, fluoxetine, and sertraline in primary care: a randomized trial. JAMA 2001; 286:2947-55.
9. Price JS, et al. A comparison of the post-marketing safety of four selective serotonin re-uptake inhibitors including the investigation of symptoms occurring on withdrawal. Br J Clin Pharmacol 1996;42:757-63.

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Simvastatin Labeling Changes

The following is a letter prepared by the PEC & sent to pharmacy & provider e-mail lists earlier in July.

Since the withdrawal of cerivastatin from the market nearly a year ago, questions have been raised about the muscle-related adverse effects associated with the remaining statins. A recently released joint clinical advisory from the American College of Cardiology, the American Heart Association, and the National Heart, Lung and Blood Institute addresses this issue. The advisory states "clinicians should consider the rates of severe myopathy as equivalent among all these approved statins."

Merck recently revised the product labeling for simvastatin (Zocor) to include detailed information gathered from post-approval clinical trials, including the recently published Heart Protection Study (Lancet 2002; 360 9326: 7-22). The Heart Protection Study included more than 20,000 patients. This labeling change provides additional information about the dose-related risk of myopathy and potential drug interactions. No FDA mandated black-box warnings were imposed and the labeling change was not the result of any significant new findings or increase in prevalence of previous findings. The change simply clarifies the risk of muscle related adverse effects with simvastatin. The following are key changes in the labeling:

- **Concomitant therapy with fibrates or niacin:** The language strengthened from 'should generally not exceed 10 mg' to 'should not exceed 10 mg' of simvastatin when used in combination with fibrates or niacin (>1g/day). Combination therapy, while desirable in mixed dyslipidemic patients, increases the risk of muscle-related adverse effects in all patients.

- **Concomitant therapy with verapamil or amiodarone:** The labeling states that the risk of muscle-related adverse effects increases from 0.06% with simvastatin alone to 0.6% when used with verapamil. The risk of muscle related adverse effects in 6% when combined with amiodarone. The labeling now states that dosing should not exceed 20 mg of simvastatin when used in combination with either verapamil or amiodarone. This interaction appears to be mediated through the cytochrome P450 system and presumably affects all 3A4 statins (atorvastatin, lovastatin & simvastatin).

- **Dose related increase in myopathy:** The labeling now enumerates the risk of muscle-related toxicity with increasing doses. The incidence rate for myopathy is estimated as 0.02% for 20 mg, 0.07% for 40 mg, and 0.3% for 80 mg of simvastatin. It is important to note that muscle-related injury is a class effect. The risk increases as the dose increases in all statins.

Clinicians should continue to monitor patients for adverse effects associated with statin therapy. Many patients are taking a combination regimen with simvastatin at doses higher than is now recommended without

apparent complications. Whether or not to adjust therapy based on the recent labeling changes is a question to be addressed by the clinician and patient, taking into consideration the benefits and risks of statin therapy.

The Department of Defense Pharmacoeconomic Center PEC Update
August 2002, Vol. 02, Issue 5, www.pec.ha.osd.mil

Barb's Barbs

5

Hormone Replacement Therapy & the WHI and HERS II Studies

LtCol Barbara Roach, USAF, MC
Air Force Medical Officer, DoD Pharmacoeconomic Center

Just a brief note this month regarding the recent developments concerning combination Hormone Replacement Therapy (HRT).

In early July, the NIH announced that it had stopped the combination estrogen/progestin arm of the Women's Health Initiative (WHI) Study several years prior to its intended completion. The estrogen only arm of the study (in women who have already undergone a hysterectomy) is still in progress. The action was taken due to evidence of an increased risk of invasive breast cancer in women taking combination therapy. The trial also found small increases in coronary heart disease, stroke, and pulmonary embolism. There were some benefits (reduced rates of hip fracture and colon cancer), but overall risk exceeded benefit.

Results of the Heart and Estrogen/Progestin Replacement Therapy (HERS II) Study, which followed patients in the 4.1 year HERS I Study for an additional mean duration of 2.7 years were also released in July. Results confirmed the initial findings of HERS I: no appreciable cardiovascular protection from HRT in older women with coronary disease.

Both studies were published in JAMA: HERS II in the **July 3, 2002** issue; and the estrogen/progestin arm of the WHI study in the **17 July 2002** issue.(As both of these studies are felt to be of landmark importance, one does not have to subscribe to JAMA to view the full articles.)

Commentary about the WHI and HERS II Findings - The American College of Obstetricians and Gynecologists (ACOG) statements on the HERS II and WHI studies are available on the **ACOG website**. (ACOG is forming an HRT task force to make clinical practice recommendations in light of the new findings.) You can also go to the **Women's Health Initiative home page** to view the National Heart Lung and Blood Institute summary of the study along with the letters sent to patients in the study. The **American Heart Association** has issued responses to the findings from both studies. There is no response yet from the **American College of Cardiology** concerning the WHI or HERS II studies.

Barb's Opinion: what does all this mean? - Do the two studies just mentioned mean that conjugated

estrogens/medroxyprogesterone (Prempro) should be removed from the BCF and all women taken off this medication? In my opinion, at least—of course not. Patients who are already on combined estrogen/progestin should discuss the reasons for which they are taking it with their providers before deciding to discontinue the medication. There is no good substitute for this medication in women who have menopausal symptoms. If the only reason someone was given HRT was for cardiovascular protection, then it can likely be discontinued. If it's being used for prevention of osteoporosis, I feel that it can likely be continued. However, other medications for osteoporosis are also available, such as the bisphosphonates and the SERMs, although the advantages of these therapies over HRT remain largely undefined. Read the ACOG statements. Remember, the absolute risk for any of these problems due to the medication is very small for any individual patient. To quote Arthur Dent*: "Don't Panic."

Barbara Roach, MD
Air Force Medical Officer, DoD Pharmacoeconomic Center
210-295-2777 or 210-295-1271; DSN 421-
barbara.roach@amedd.army.mil

***Editor's Note:** Arthur Dent is a character in the "Hitchhiker's Guide to the Galaxy," a 5-book trilogy (yes, really) by British humorist Douglas Adams.

The Department of Defense Pharmacoeconomic Center PEC Update
August 2002, Vol. 02, Issue 5, www.pec.ha.osd.mil

Questions & Answers

6

Notifying Prime Vendors about Usage Requirements & Recent Questions Regarding Blood Glucose Test Strips

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Notifying Prime Vendors about Usage Requirements

CDR Brian Kerr, USN
Acting Chief, Prime Vendor Branch
Pharmacy Group, Defense Supply Center Philadelphia

Q.

Is there a mechanism in place where we notify our Prime Vendors if a product has become mandatory, or has been added to the Basic Core Formulary? For example, when Prilosec™ (omeprazole) was removed from the Basic Core Formulary and Aciphex™ (rabeprazole sodium) added, did a DOD entity such as Defense Supply Center Philadelphia (DSCP) or the Pharmacoeconomic Center notify our Prime Vendors about this potentially large shift in product sales…or is up to the individual units to do so?

A.

The Pharmaceutical Business Unit at DSCP does notify our pharmaceutical prime vendors when a national contract item is awarded (as a courtesy heads-up); however, it is the responsibility of the individual customers to notify their prime vendor of their requirements (usage data) and to allow them sufficient time to adjust their inventories.

The prime vendor is not required to stock the item until the customer requests it. According to the statement of work for our prime vendor contracts, “Usage data is that information provided by the MTF to the contractor, which will establish the contractor’s inventory levels on individual products for that facility.” The wording is slightly different in the statement of work for the newer (Generation II) prime vendor contracts, presently covering Europe and soon-to-be TriCare Northeast, than in the older contracts, but basically they both say that the MTF shall notify the contractor at least 30 days before the contractor is required to stock a product.

A reminder to notify the Prime Vendor is placed in every notice sent out to the field from DSCP on every new national contract award.

Recent Questions Concerning Blood Glucose Strips

LCDR Ted Briski, MSC, USN
Navy Pharmacy Officer, Director of Contracting Activities, DoD PEC

Below are the answers to questions we have received over the last few weeks.

Q.

Are Precision QID strips the only Precision strip allowed to assure compliance with the Basic Core Formulary (BCF)?

A.

No. Precision QID strips are in the beginning of a phase-out; Precision Extra strips are being phased-in. The QID strips will continue to be available throughout the transition process to assure patients are not inconvenienced. Either Precision product complies with the BCF.

Q.

Are Precision meters and strips the only BG products I can dispense?

A.

Absolutely not. You must make Precision products available to assure uniform patient access. If you have patients with special needs or patients who are not suitable candidates for the Precision product, then an alternative product can and should be supplied.

Q.

Will a second BG strip be added to the BCF?

A.

There is no current plan to recommend that the DoD Pharmacy and Therapeutics Committe add a second strip to the BCF. It is up to individual MTFs to decide if they require an additional strip on their local formulary. You might be interested in knowing that Lifescan Ultra is the strip most commonly dispensed by retail network pharmacies.

Q.

What is the current utilization of BG strips within the MTFs?

A. The western regions have standardized on Precision strips, which make up more than 70% of their BG strip utilization. Regions 1,2 and 4 are heavy users of the Roche strip, with Region 6 split 50/50. If Precision strips gain a few more percentage points of market share, DoD will be able to take another $0.05 off the price of each Precision strip purchased.

Ted Briski, Pharm.D., MBA, BCPS

Director of Contracting Activities
DoD Pharmacoeconomic Center
210-295-2771 or 210-295-1271; DSN 421-
ted.briski@amedd.army.mil

The Department of Defense Pharmacoeconomic Center PEC Update
August 2002, Vol. 02, Issue 5, www.pec.ha.osd.mil

Waiverable Medications in Aircrew Members

LtCol Ed Zastawny, USAF, BSC
Air Force Pharmacy Officer, DoD Pharmacoeconomic Center

THANKS to COL (ret) Dr. "Beek " Vanderbeek, USAFSAM, LTC (Dr.) Joe McKeon, Ft Rucker, AL, CDR (Dr.) Jeff Brinker, NOMI, for their help and review of this article.

In an MTF, personnel are often faced with the situation where an aircrew member presents a prescription for a non-formulary item. Although there may be suitable **clinical** alternatives on the formulary, the non-formulary item is required **operationally** so the aircrew member can continue to fly. Is there somewhere we can look to find out what is waiverable and what is not? Are there differences between the different services? [Need you ask? Yes, there **ARE** differences between the services. DoD is trying to change things, but it's a tough process.]

First, let me try to clarify a few things. Although medications can certainly impair a person's ability to fly an airplane, the condition being treated is often more of a factor in "grounding" a pilot or aircrew member than the drug itself. For example, amoxicillin is a relatively benign drug used commonly for otitis media (middle ear infection). The drug is safe, but the middle ear infection may impair the ability to fly. The pilot can fly when the otitis resolves, even though he or she may have 4 or 5 more days to complete the course of antibiotics.

Although we're all part of one Department of Defense, the three services have different regulations and guidance regarding the treatment of aircrews, what meds they can take, which ones are waiverable, and what processes they must go through to return to duty (flying). In general, any medication 'grounds' an aircrew member, even if it's a waiverable medication. An aircrew member on a waiverable drug is returned to flight status only after an observation period. Drugs for aircrew members must be prescribed by, or with the knowledge of, a flight surgeon.

ARMY - Army regulation 40-8 governs temporary restrictions due to exogenous factors (including medications). The regulation can be found on line at **www.usapa.army.mil/pdffiles/r40_8.pdf**. Medication policy letters for the Army are available on-line at: **usasam.amedd.army.mil/_AAMA/policyLetter.htm**. The medication policy letters break medications down into 4 classes: over-the counter medications; no waiver action required or information only, chronic use; chronic use requiring waiver; and mandatory disqualifying medications.

Included on the list of mandatory disqualifying medications: alcohol within 12 hours of flying, antihistamines (including cetirizine but excluding non-sedating antihistamines), barbiturates, and mood-ameliorating,

tranquilizing, or ataraxic drugs (see policy letter for complete list). Smoking is not on the list of mandatory disqualifying medications, but is discouraged—besides its overall adverse health effects, smoking increases the carbon monoxide content in the blood and decreases physiologic performance.

NAVY - **Navy Instruction 3710 (NATOPS General Flight and Operating Instructions),** Chapter 8.3.2.5, includes information governing Navy aircrew members. Also available on the web: **Naval Operational Medicine Institute (NOMI) guidance regarding medications in Navy flyers**. The guidance and list of waiverable medications is a bit longer than the Army's list. The guidance addresses specific topics such as antimicrobials, antihypertensives, anti-hyperlipidemics, immunizations, and the (ever popular) miscellaneous category.

AIR FORCE - **Air Force Instruction 48-123** covers use of medications in Air Force aircrew members. This extensive (300+ pages) instruction governs medications, medical conditions, medical standards, etc. affecting aircrew members as well as special duty operators, missile crews, ground controllers, and so forth. The part of this AF instruction (AFI) relating specifically to medications is A7.32, Medication (p. 162). Medications may be 1) approved for use without medical consultation, 2) approved for use by a flight surgeon without removal from flying duty, 3) require a waiver (specifies level of the command structure that waiver must come from), or 4) not waiverable. Medications listed as not waiverable may be approved or granted a waiver after physiological testing at the USAF School of Aerospace Medicine at Brooks AFB.

Waiverable Medications on the Basic Core Formulary - Although the presence of specific medications on aircrew waiverable lists is taken into account when choosing drugs for the DoD Basic Core Formulary (BCF), the cost-effectiveness analysis done for the entire beneficiary population (most of whom don't fly planes!) may not always choose the waiverable medication. In addition, a medication that's 'waiverable' in one service may not be 'waiverable' in another service. BCF guidance and national pharmaceutical contracts acknowledge that it may be necessary to procure a non-formulary or non-contract drug, if needed to meet the clinical and/or operational needs of a patient.

Ed Zastawny, Pharm.D., BCPS
DoD Pharmacoeconomic Center
210-295-2779 or 210-295-1271; DSN 421-
edward.zastawny@amedd.army.mil

The Department of Defense Pharmacoeconomic Center PEC Update
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New Drug Watch

Angela Allerman
Clinical Pharmacy Specialist
DoD Pharmacoeconomic Center

Quick Links

It has been a slow summer for new drug approvals, so this month's column will take a detour and instead review drugs that are far along in the research pipeline and pending FDA approval that could potentially impact the DoD, either financially or through advances in therapies for several disease states. We'll also catch up on some new generics, new indications & formulations, and a few new treatment guidelines. Next month, I'll detail the new drugs discussed at the August 2002 DoD P&T Committee meeting.

Drugs in the Pipeline

Several innovative products (and some "me-too" ones) are likely to be approved by the FDA in the next year. How can we predict when a drug will obtain final FDA approval? If I had a reliable answer to that, I'd be sitting on the beach in Australia, admiring my ocean-front mansion. It's an unpredictable process. When the FDA designates a drug as "approvable" this does not mean that the drug has received final approval. The FDA may still require additional safety and efficacy data, or there may be discussions with the manufacturer on the final product labeling or packaging, issues which could take months to resolve.

Useful sources for monitoring new drug approvals include the **FDA website** and other medical/pharmacy news organizations websites, such as **Medscape** or **Pharmscope** (these last two websites are free, but do require registration). The **FDA Center for Drug Evaluation and Research website** is of course the definitive source for information on newly approved drugs (but not biologics—try the **FDA Center for Biologics Evaluation & Research**), new generic drugs, and other regulatory information, including patent expirations, product withdrawals, "Dear Doctor" letters, and patient information brochures. The sheer size of the FDA website can sometimes make information hard to find. Useful starting pages include the **CDER new and generic drug approvals page**, the **"What's New" page for FDA Advisory Committees**, and the **FDA Advisory Committee page under Dockets** (links to advisory committee minutes and transcripts).

The following table lists drugs the FDA has deemed "approvable", those recommended by FDA Advisory Committees for approval, or drugs far along in the pipeline. Although these drugs are likely to be formally approved sometime this year, there is no 100% guarantee that any of these agents will reach the marketplace

soon. On occasion, medications approved by the FDA are severely delayed in reaching the marketplace, as the pharmaceutical company may lack a marketing partner to successfully introduce the drug, expected sales may be too low to garner enthusiasm, or problems with manufacturing may mean that the company cannot ensure an adequate supply.

Generic Name	Trade Name	Manufacturer	Drug Class	Indications	Comments
Approvable Agents					
Dutasteride	Avolve(?)	Glaxo SmithKline (GSK)	5a-reductase inhibitor	BPH; company is investigating use for reducing the risk of acute urinary retention	Approved since 11/01, but not marketed
Alfuzosin	UroXatral	Sanofi-Syntheloabo	a1 blocker	Symptomatic BPH	Approvable 10/01
Escitalopram	Lexapro	Forest	selective serotonin reuptake inhibitor (S isomer of citalopram)	Depression	Approvable 01/02; likely to come to market by 3rd quarter 2002
Rosuvastatin	Crestor	AstraZeneca	Statin	Hyperlipidemia	Approvable 01/02
Tadalafil	Cialis	Eli Lilly and Icos	Phosphodiesterase 5 inhibitor	Erectile dysfunction	Approvable 04//02; delayed due to manufacturing problems
Tibolone	Xyvion	Akzo Nobel	Tissue specific synthetic steroid	Osteoporosis	Approvable 04/01
Teriparatide	Forteo	Eli Lilly	Parathyroid hormone analog	Osteoporosis	Approvable 04/01

Pramlintide acetate	Symlin	Amylin Pharma	Synthetic amylin, a hormone secreted with insulin from the pancrease	DM patients using insulin	Approvable 10/01
Ziconotide	Prialt	Elan	Analgesic isolated from the venom of an ocean-dwelling snail	Chronic intractable pain	Approvable 06/00
Agents recommended for approval by an FDA advisory committee					
Telithromycin	Ketek	Aventis	Third generation macrolide	Gram positive respiratory infections	Recommended for approval 04/01 Co. has completed a large trial requested by the FDA
Other agents with New Drug Applications filed in the past year or in late phase III trials					
Acamprosate		Forest	Analog of homotaurine, GABA agonist	Maintenance of abstinence for patients with chronic alcohol dependence when used with psychosocial or behavioral counseling	Not recommended for approval by FDA advisory committee on 2/02 One additional safety/efficacy study required
Aripiprazole		BMS	Atypical antipsychotic	Schizophrenia and related disorders	Phase III clinical trials
Duloxetine	Cymbalta	Lilly	Dual 5-HT/NE re-uptake inhibitor	Depression; also under study for stress incontinence	Phase III clinical trials

Eletriptan	Relpax	Pfizer	5-HT agonist (triptan)	Migraine headache	Phase III clinical trials
Eplerenone		Pharmacia	Aldosterone inhibitor	Hypertension	Phase III clinical trials
Ezetimibe	Zetia	Merck / Schering Plough	Cholesterol absorption inhibitor	Hyperlipidemia	Phase III clinical trials
Inhaled insulin	Exubera	Pfizer / Aventis	Inhalational insulin	Diabetes	Phase III clinical trials
Omapatrilat	Vanlev	BMS	Vasopeptidase inhibitor	CHF and HTN	Phase III clinical trials; FDA advisory committee review on 7/19/02
Parecoxib		Pharmacia	IV COX-II (pro-drug of valdecoxib)	Acute Pain (dental surgery, episiotomy)	NDA filed 10/00
Tiotropium	Spiriva	Boehringer Ingelheim	Ipratropium derivative	COPD	NDA 12/01
Vardenafil		Bayer / GSK	Phosphdiesterase 5 inhibitor	Erectile dysfunction	NDA pending; delayed due to additional study requirements

New Generics

- *Tramadol 50 mg tablets* are now approved and are available from several generic companies, including Alpharma, Caraco, Eon, Mylan, Teva, and Watson
- *Ciprofloxacin 100-, 250-, 500- and 750 mg tablets* received FDA approval on 8 Jul 02 but launch date is uncertain
- *Amoxicillin and clavulanate potassium* is now available from Geneva Generics in several tablet and oral suspension strengths
- *Misoprostol 100- and 200-mcg tablets* are now available from Ivax
- *Tizanidine HCl 4 mg tablets* are now available from Eon Labs
- *Lisinopril and lisinopril/HCTZ combo products* are now available from several generic companies

New Indications

- *Darbepoetin (Aranesp)* was approved in July for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies
- *Gabapentin (Neurontin)* received approval for managing post-herpetic neuralgia
- *Botulinum toxin Type A (Botox)* has been approved for treating brow furrows or the vertical creases between the eyebrows

New Formulations

- *Risedronate (Actonel)* is now available in a 35-mg tablet for once weekly dosing for the prevention or treatment of osteoporosis
- *Methylphenidate (Concerta)* is now available in a 27-mg extended release tablet
- *Pravastatin (Pravachol)* 80-mg tablets were recently approved

Angela Allerman, Pharm.D., BCPS
DoD Pharmacoeconomic Center
210-295-2790 or 210-295-1271; DSN 421-
angela.allerman@amedd.army.mil

The Department of Defense Pharmacoeconomic Center PEC Update
August 2002, Vol. 02, Issue 5, www.pec.ha.osd.mil

PDTS Corner

9

Update on the Pharmacy Data Transaction Service

Quick Links

Data Integrity Effort from the Field

By CAPT Roger Hirsh MSC USN, Pharmacy Service Line Leader (translation: Pharmacy Dept Head), Naval Medical Center Portsmouth, and Hector Morales, PDTS CSSC Help Desk Manager, ACS

The following are some of the efforts CAPT Hirsh at Portsmouth Naval Hospital has taken to significantly decrease the number of Data Integrity issues at his and other sites. He recently gave us permission to share these efforts with all of you.

He spent part of a week in July at Charleston NH running reports and cleaning up drug files. After completing his review and edit of 3,500+ orders from the system order set file, he was able to say that Charleston conforms to METRIC UNIT. He also began a review of default sigs. A review of the drug file showed most defaults set correctly, though by putting a "1" in the package size field, the cost display is confusing. Leaving it blank for a metric unit=default unit is clearer.

A few more hints on dealing with the PDTS "Data Integrity" report by approaching it as a system problem:

1. Sort the report by drug to find your high frequency problems.

2. Under ADN, Review the package size/metric unit/default unit fields to make sure they properly correspond.

3. Check the default sig under FRM. The sig needs to be correct, using CHCS short codes whenever applicable so CHCS will calculate the days supply correctly.

4. Test the sig under RX to be sure it defaults to the number of days/units you desire.

5. Recognize that some things will be persistent problems, such as the DOD deployment supply of 180 days creating a soft edit return message for exceeding the 110 max days supply. Same for OCPs.

6. Having done the above, which are all one-time fixes, there will still be a number of outliers, including refills, etc. While it is impractical (not impossible) to edit or modify refills, expired Rxs, and so forth, the important part is to fix the new Rxs.

The outliers should be re-sorted by provider, which requires running an ad hoc to match PDTS number, RX number, drug, sig and provider. Drugs which are fixed in the drug file may be set up incorrectly in order sets. An ad hoc report of order sets sorted by entity:entity, name, created for, will yield a report to be done as a flat file and/or dumped into Excel (my preference) or Access. Sorting by entity (drug) will show you which order sets may need to be modified. The report does not show the actual SIG, so you must review each relevant order set. Some may be shared, so the provider who created the set may not be one of the providers on your initial report of Rxs.

The next issue is to edit the order set, which can only be done if you are the creator of the set OR have access to the file to switch the creator to yourself, then edit the set and switch it back when done.

A Couple of Examples

Inhalers

Metric unit: GM
PKG size: 17 (albuterol)
Default unit: 17GM/INH
Prescribed as: #1, 2, 3 etc.
Local Cost: per 17GM inhaler [the price corresponds to the default unit, not the metric unit unless they are the same (tab, cap, ml)]
Albuterol default SIG: INHALE 1-2 PUFFS Q4-6H UD #1 RF3
Days supply will default to 1 and PDTS will list the Rx number on your Data Integrity report.
WHY? CHCS recognizes 1-2 and recognizes Q4-6H. At max of 12/day, 17 is a 1+ day supply.
FIX: Change default SIG to INH 1-2 PF Q4-6H UD #1 RF3 Now CHCS recognizes INH and PF and will not assume a direct calculation, but will default to 30 days. PDTS will leave you alone.
LESSON: All default sigs and order sets should use the PF instead of puff to get a 30 day default.

Oral Contraceptives

Metric unit: tab
PKG size: 28
Default unit: 28TAB PACK
Prescribed as: #1,2,3,6, etc.
Local Cost: per cycle.
Default SIG: TAKE PER PACKAGE DIRECTIONS #6 RF1 -
PDTS receives #168, defaulted to 30 days supply, reject for

excessive dose
FIX: T1 TAB QD PER PACKAGE DIRECTIONS #6 RF1 - PDTS receives #168, calculates 168 days supply, initial override must occur for excessive days supply, but won't show up as data integrity issue. Since this is a DOD policy, we'll have to do the overrides until policy or PDTS changes. Meanwhile, a UDK with the override might be possible, but I haven't tried it yet.

7. The last problem is UDKs, which are very tricky to fix. Like order sets, the CHCS file has the name, editor, etc, but doesn't have any of the affected drugs, since the drug name isn't part of the UDK, though a synonym probably is. Once the default sigs and order sets are fixed, most UDKs will self correct. In general, they are set up to use default directions and quantities, so having the "standard" SIG and qty in the drug file is important.

On Line Patient Profiling

By Crystal Little, PDTS Project Officer, ACS

There are still some sites not using the On Line Patient Profile option. Some were not aware that it was available to them. Please contact your System's office immediately if you do not have the capability to access On Line Patient Profile.

TRY OUT ON-LINE PATIENT PROFILING—YOU'LL LIKE IT!

To access the On Line Patient profile for PHARMACY follow menu path PHR>OPM>PM>PRI. Enter the PATIENT name at the SELECT PATIENT /RX# prompt. Then choose P for combined CHCS and PDTS profile. Choose the number corresponding to the time frame (30 days, 60 days, etc) you wish to view. The profile can be viewed on the screen, sent to a printer or sent to your CHCS Mail Box. If a response is not received with in 6 seconds then CHCS will display "No profile response received from the PDTS" and then will allow the user to send the profile to the mailbox or a printer when the connectivity has been reestablished.

Here is what Ms. Nancy Radebaugh at Ft Hood says about the new On Line Patient Profile option:

> "MAJ Ford asked me to contact you concerning our utilization of this powerful option for patient medication profiling. As ambulatory pharmacists, we see patients in the Medication Management, Disease State Management and Anticoagulation Clinics. The ability to review a patient's complete medication profile (particularly as so many of our beneficiaries are seen in multiple facilities—both military and civilian) is an incredible asset as we review treatment regimens for efficacy, toxicity and the ever problematic drug interactions. I personally use this option with essentially every patient I interview!"

To access the On Line Patient Profile for CLINICAL users, after entering in ORE, enter the patient name and requesting location. At the Action prompt enter DPRX (Display PDTS Patient Profile). Choose the number corresponding to the time frame (30 days, 60 days, etc) wished to view. The profile can be viewed on the screen, sent to a printer or sent to your CHCS Mail Box. If a response is not

received with in 6 seconds then CHCS will display “No profile response received from the PDTS” and then will allow the user to send the profile to the mailbox or a printer when the connectivity has been reestablished.

PDTS Management Reports

By COL (Ret) Roger Williams, PDTS CSSC Clinical Support Supervisor

When the PDTS was first developed one of its objectives was to establish a method to report on the data maintained in the central repository. While the CSSC has had this capability from the beginning, there was no secure way to extend this functionality out to the field. That has all changed. Now, using Business Objects software via an Internet Web Server, managers at various levels of DoD Pharmacy are acquiring access to the PDTS data warehouse and the capability of generating their own management reports.

To assist individuals in learning Business Objects, the CSSC is now offering training sessions at Fort Sam Houston. The classes run for two days with each session consisting of one day of classroom presentations while working with the software and one day orientation in the CSSC to observe how Business Objects is being utilized. Individuals interested in attending a session will need to obtain local funding.

In addition to pharmacy managers gaining direct access to PDTS data, the CSSC continues to provide reports upon request. While most Adhoc reports are now run in Business Objects, there are still some of the standard reports that continue to be utilized due to the specialized data they retrieve. For information about requesting a report or scheduling a training session in Business Objects please refer to the **PDTS section of the PEC Web Page**.

Top 10 Level 1 Drug-Drug Interactions by Point of Service

By COL (Ret) Roger Williams, PDTS CSSC Clinical Support Supervisor

The feature in PDTS that enhances patient safety is the process of conducting Prospective Drug Utilization Reviews (ProDURs). PDTS conducts on-line ProDURs (clinical screens) on all medications dispensed, regardless of the DoD point of service the patient used to have the prescription filled. Pharmacy personnel need to be aware that with the activation of PDTS, the number of clinical screenings could increase depending on how frequently patients use multiple prescription sources. PDTS clinical screens are performed only on those medications the patient obtains from outside of the dispensing site’s host cluster. It will not duplicate clinical warnings generated from within the CHCS host system.

For further information about the PDTS DURs, see **my article in the Mar 2002 PEC Update**.

Top 10 Potential Level 1 Drug-Drug Interactions in MTFs, Jun 2002

Rank	Medications involved	#
1	Ibuprofen / Ketorolac tromethamine	274
2	Ketorolac tromethamine / Naproxen	151
3	Nitroglycerin / Sildenafil citrate	84

4	Ketorolac tromethamine / Rofecoxib	67
5	Celecoxib / Ketorolac tromethamine	53
6	Isotretinoin / Minocycline HCl	46
7	Itraconazole / Simvastatin	30
8	Ketoconazole / Simvastatin	30
9	Amiodarone HCl / Gatifloxacin	27
10	Indomethacin / Ketorolac tromethamine	27

Top 10 Potential Level 1 Drug-Drug Interactions in the Retail Network, Jun 2002

Rank	Medications involved	#
1	Ibuprofen / Ketorolac tromethamine	97
2	Nitroglycerin / Sildenafil citrate	83
3	Ketorolac tromethamine / Naproxen	47
4	Celecoxib / Ketorolac tromethamine	45
5	Isotretinoin / Minocycline HCl	43
6	Ketorolac tromethamine / Rofecoxib	42
7	Ketoconazole / Simvastatin	38
8	Entacapone / Selegiline HCl	31
9	Itraconazole / Simvastatin	31
10	Aspirin / Ketorolac tromethamine	23

Top 10 Potential Level 1 Drug-Drug Interactions in the NMOP, Jun 2002

Rank	Medications involved	#
1	Nitroglycerin / Sildenafil citrate	59
2	Amiodarone HCl / Gatifloxacin	20
3	Celecoxib / Ketorolac tromethamine	14
4	Ketorolac tromethamine / Rofecoxib	14
5	Gatifloxacin / Sotalol HCl	9
6	Itraconazole / Simvastatin	7

7	Ketoconazole / Simvastatin	7
8	Acetazolamide / Topiramate	6
9	Amiodarone HCl / Moxifloxacin HCl	6
10	Atorvastatin calcium / Ketoconazole	6

The PDTS Customer Service Support Center

The PDTS CSSC strives to provide world-class customer support to all Military Health System users while enhancing the operational effectiveness and ensuring the quality of information maintained within the Pharmacy Data Transaction Service. The PDTS CSSC comprises the Pharmacy Benefit Operations Division of the PEC and is co-located with the Clinical Operations Division of the PEC at Ft. Sam Houston, TX.

The PDTS CSSC has an e-mail address for questions, comments, concerns, or report requests:

PDTS@cen.amedd.army.mil

Drop us an e-mail! We will respond via e-mail or call you within 1 business day.

Or call the PDTS CSSC at:

- DSN: 471-8274
- Toll-free commercial:
  1-866-275-4732
  (1-866-ASK4PEC)
- Local commercial (San Antonio):
  (210) 221-8274
- OCONUS:
  (AT&T access code)+866-275-4732

Need more information?

Many materials pertaining to PDTS, including trouble call procedures, the PDTS Report Request Form, business rules, and interchange control documents (ICDs), are available in the PDTS section of the PEC website. Just go to **www.pec.ha.osd.mil/pdts/pdts_documents.htm** and browse through the options on the left-hand navigation bar.

In addition, many articles on various aspects of PDTS and the PDTS CSSC have been published in recent issues of the *PEC Update*. Please visit the PEC Update page on the PEC website - **www.pec.ha.osd.mil/ac03000.htm** - for back issues.

We are here to serve you 24 Hours a Day, 7 days a Week.